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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,536	11/29/2001	Michael R. Gambini	715-009111-US(PCT)	7337
35411	7590	08/14/2003		
KILYK & BOWERSOX, P.L.L.C. 3603 CHAIN BRIDGE ROAD SUITE E FAIRFAX, VA 22030			EXAMINER	
			REDDING, DAVID A	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 08/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,536	GAMBINI ET AL.	
	Examiner	Art Unit	
	David A Redding	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 6-10, 12, 16-18, 29 and 30 is/are allowed.
- 6) Claim(s) 1-6, 11, 13-15 and 19-28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9, 12, 15</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 14,20-22,27,28 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 5,736,333 (Livak et al.).

In the specification the primary focusing means is disclosed as comprising a vial lens (2b) (pp.8,lines 14-19); the first means and second means is disclosed as comprising a single beam splitter (pp. 9, line 30); the emission focusing means is disclosed as comprising a detector lens or reflector lens; and the detector is disclosed as a charge-coupled device (CCD) (see figure 1).

Livak et al. discloses an optical instrument combined with a DNA thermal cycling device for monitoring in a real-time mode the DNA concentration (col.3, lines 40-53; col. 4, lines 39-52; col.1, lines 63- col.2, lines 1-3). The instrument is shown in figures 1 and 2. The instrument comprises a light source (2) as claimed in the form of a laser, a beam splitter (40) which is considered to be equivalent to the claimed first and second means, a vial lens (8) is associated with each sample vial and considered to be equivalent to the primary focusing means (figure 1), a detector lens (44) which reads on the claimed emission focusing means, and a CCD detector. The embodiments which are considered to anticipate claims 4 and 5 are illustrated in figure 1.

Further the reference discloses the use a fluorescent reference emitter (internal reference) and analyzer for normalizing the measurement based on the internal reference (col. 12, lines 26-44).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5,736,333 (Livak et al.) in view of EP 0 640 828 A1.

The Livak et al. patent is silent as to the use of an excitation filter with the light source. The patent does disclose the use of an emission filter (42). The EP patent discloses an apparatus similar to the claimed invention and the device disclosed in Livak et al. The EP patent discloses that the light source for the fluorescence excitation and emission measurements can be monochromometers and lasers (col.30, lines 1-10).

Further the EP patent discloses that an emission filter can be used with the light source to obtain the desired excitation wavelength. Accordingly, it would have been obvious to one skilled in the art to use an excitation filter with the light source in Livak et al. in order to fine tune the excitation wavelength in view of the known practice disclosed in the EP patent.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 640 828 A1 in view of US 2002/0146688 A1 (KINJO).

Figure 15 in the EP reference illustrates the claimed invention, except the EP device uses a UV light source and not the Halogen lamp as claimed. The KINJO reference discloses a similar apparatus as claimed using a halogen light source with light converging means (reflector) for fluorescence assay of PCR (col.4, paragraph #0070). Accordingly it would have been obvious to one skilled in the art to use a halogen light source in place of the light source (14a) in the EP patent in view of the known use disclosed in the KINJO publication.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5,736,333 (Livak et al.).

Livak et al. discloses the use of a second fluorophore as an internal reference (col.12, lines 26-44).

In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) Although the reference did not disclose a plurality of ribs, the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.).

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Accordingly, in the absence of unexpected results the mere duplication of the internal reference disclosed in Livak et al. is considered to be patentably insignificant.

8. Claims 19, 23-26, are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5,736,333 (Livak et al.) in view of EP 0640828 A1.

The EP patent discloses the use of a control tube 26C to provide a constant fluorescence source against which cycle to cycle measurement variations, due to minor temperature variations or drift (col.21, lines 6-28). Accordingly it would have been obvious to one skilled in the art to correct the instrument for drift by using a fluorescent reference emitter in the Livak et al. in view of the known practice disclosed in the EP reference.

Allowable Subject Matter

9. Claims 6-10,12,16-18,29 and 30 are considered to be allowable over the prior art of record.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Redding whose telephone number is 703-308-3910. The examiner can normally be reached on M,T,Th,Fr, 7:30-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



David A Redding
Primary Examiner
Art Unit 1744

D.A.R.
August 5, 2003